# Operator’s Manual

2023486-201rC

| REVISION HISTORY | | |
|---|---|---|
| **Part number** | **Date** | **Comment** |
| 2023486-201 Rev A | October 2006 | Initial Release |
| 2023486-201 Rev B | December 2006 | AHA Guidelines added |
| 2023486-201 Rev C | July 2007 | Revised for misc. minor updates, new symbols and EMC table added |

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# SECTION 1: INTRODUCTION

## OVERVIEW

Become familiar with the controls and how to use the AED PRO properly before operating the product.


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## AED PRO DESCRIPTION

The AED Pro is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. The AED guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. At the discretion of Advanced Life Support (ALS) personnel, the AED Pro can be converted to manual override mode, and deliver a shock by pushing the SHOCK button. The AED Pro can also provide non-diagnostic ECG monitoring.

## INDICATIONS FOR USE / INTENDED USE

The AED PRO with STAR Biphasic Waveform is intended to be used by medical professionals who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED, and manual defibrillation. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest that are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED Pro should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy; or when in manual override mode, ALS personnel will monitor the ECG display and deliver a shock by pushing the shock button to deliver therapy.

***WARNING:*** When the patient is a child or infant under 8 years of age or weighs less than 55 lbs (25kg), the AED PRO should be used with the Model 2019199-003 Pediatric Attenuated Defibrillation Electrode Pads. Therapy should not be delayed to determine the patient's exact age or weight.


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# SAFETY TERMS AND DEFINITIONS

## BEFORE OPERATING THE RESPONDER AED PRO

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Responder AED Pro.

# SAFETY TERMS AND CONDITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:

***DANGER***: This alert identifies hazards that will cause serious personal injury or death.

***WARNING:*** This alert identifies hazards that may cause serious personal injury or death.

***CAUTION:*** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

# SAFETY ALERT DESCRIPTIONS

The following is a list of Responder AED Pro safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the AED Pro.

***DANGER***: Fire and Explosion Hazard
Do not use the AED Pro in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

***WARNING:*** Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not use in water
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads and ECG electrodes clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

***WARNING:*** Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

***WARNING:*** Lithium Sulfur Dioxide Battery 2023681-001 (9145) is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

***WARNING:*** Shock Hazard
Do not disassemble the AED Pro! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.


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***CAUTION:*** Temperature/Humidity/Pressure Extremes
Exposing the AED Pro to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED Pro to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED Pro; if the daily self-test determines environmental conditions outside of the AED Pros operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED Pro to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.

***CAUTION:*** Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

***CAUTION:*** Battery Disposal (Model 2023681-001)
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

***CAUTION:*** Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by GE may cause the AED Pro to function improperly during a rescue.

***CAUTION:*** Damaged or Expired Pads
Using pads that are damaged or expired may result in improper AED Pro performance.

***CAUTION:*** Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED Pro, do not operate wireless radiotelephones within 2 meters of the AED Pro – turn power OFF to the radiotelephone and other like equipment near the incident.

***CAUTION:*** Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED Pro has pacemaker detection and rejection, however, with some pacemakers the AED Pro may not advise a defibrillation shock.[1]

Placing Pads:
- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

***CAUTION:*** Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause the AED Pro to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

***CAUTION:*** Systems Statement
Equipment connected to the analog and digital interfaces must be certified to the respective IEC Standards (i.e. IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

***CAUTION:*** Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

***CAUTION:*** Environment of use
Responder AED Pro is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

[1] Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.


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***CAUTION:*** Cold Environments
If the AED Pro is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

***CAUTION:*** Not a Patient Monitor
The AED Pro is not a true patient monitor with the requisite alarms. Medical personnel should attend patients at all times while the AED Pro is in use.

***CAUTION:*** The AED is programmed with software that has been tested to work with versions of ServiceLink and RescueLink that are included with the AED. When using older versions of ServiceLink and RescueLink to communicate with this AED, there may be features described in this manual that are not available to be used. Also, when communicating with an older AED with the version of ServiceLink and RescueLink included with this new AED there may be features described in this manual that cannot be used. The software in most cases will give an error message when incompatibilities occur.

## SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the AED Pro, or on its optional components. Some of the symbols represent standards and compliances associated with the AED Pro and its use.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED Pro.

Attention!: Identifies important information in this manual, on the AED Pro, or on its component parts regarding the safe and proper use of the AED Pro.

Defibrillator Proof Type BF Equipment: The AED Pro, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

0086

**IP24** The AED Pro is protected against the effects of splashing water in accordance with IEC 60529.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

International symbol for ON. Open the lid to turn on the AED Pro.

Open the lid to turn ON the AED Pro.

Indicates the AED Pro battery status. The illuminated areas indicate the remaining battery capacity.

Indicates AED Pro requires maintenance by authorized service personnel.

When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.


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The Z-bar provides a relative visual indicator of the total transthoracic impedance between the two defibrillation pads.

A red indicator with a BLACK X means the Responder AED Pro requires operator attention or maintenance, and is not RescueReady. This symbol will be referred to as **RED** in the remainder of this manual.

A green indicator without a BLACK X means the Responder AED Pro is RescueReady. This symbol will be referred to as **GREEN** in the remainder of this manual.

Use pads by this date; install battery by this date.

Date of manufacture.

Date of factory recertification (R)

Latex Free.

Disposable. Single patient use only.

Tear here to open.

Do not recharge battery.

1. Position of pads on the chest of patient.

2. When pads on screen are flashing, check defibrillation pads. The pads are missing, not connected or have compromised functionality.

Dispose of properly in accordance with all state, province, and country regulations.

Do not incinerate or expose to open flame.

Explosion Hazard: Do not use in the presence of a flammable gas, including Concentrated oxygen.

Upper and lower temperature limits.

Device Model Number. Battery Model Number.

Serial Number

Lot Number

**Rev** Revision


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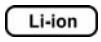
Default start-up screen

Lithium Sulfur Dioxide




Lithium Ion

Additional information is provided in the AED Pro Operator's Manual.

Points to important information regarding the use of the AED Pro.

Lift Here

Manufacturer

Authorized European Representative

Indicates placement of ECG leads and electrodes.

Symbol for the marking of electrical and electronic equipment that must be recycled.

Fragile; handle with care

Keep away from rain. (Keep dry)

This way up

Stacking limit by number

General symbol for recovery/recyclable

Humidity Limitations

Atmospheric Pressure Limitations

In November 2005, the American Heart Association (AHA) and European Resuscitation Council (ERC) released new guidelines for CPR and defibrillation. This symbol indicates that the AED contains the new AHA/ERC guidelines for CPR and defibrillation.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# SAFETY AND PERFORMANCE STANDARDS

## AED PRO MODELS 2023440

The AED Pro has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Responder AED Pro Model 2023440 and pads conform to the applicable requirements of the following:

**CE**
CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union

**ETL**
Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

**Electrical, Construction, Safety and Performance**
IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
IEC 60601-1-4 (2000)
ANSI/AAMI DF-39 (1993)

**Electromagnetic Compatibility (EMC**)
IEC 60601-1-2 (2001)
IEC 60601-2-4 Section 36
ANSI/AAMI DF-39(1993) Section 3.3.21


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## OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the AED Pro must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the AED Pro.
- Training in manual defibrillation
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

***Note:*** Keep valid certificates of training and certification as required by state, province, or country regulations.


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# SECTION 2: GETTING STARTED

## OVERVIEW

This section presents information on unpacking and setting up the AED Pro


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## UNPACKING AND INSPECTING

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

## ENVIRONMENTAL OPERATING AND STANDBY CONDITIONS

See Section 6 – Technical Data, Parameters, Environmental Operation and Standby Conditions.

**CAUTION:** Temperature/Humidity/Pressure Extremes
Exposing the AED Pro to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED Pro to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED Pro; if the daily self test determines environmental conditions outside of the AED Pro's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED Pro to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.


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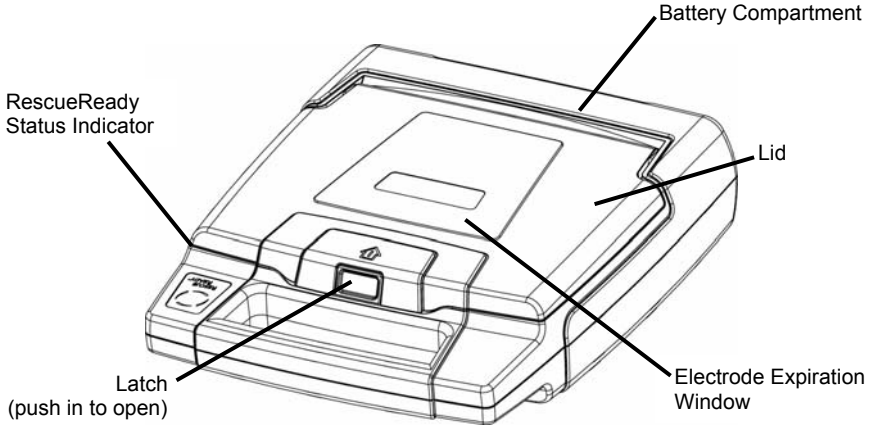
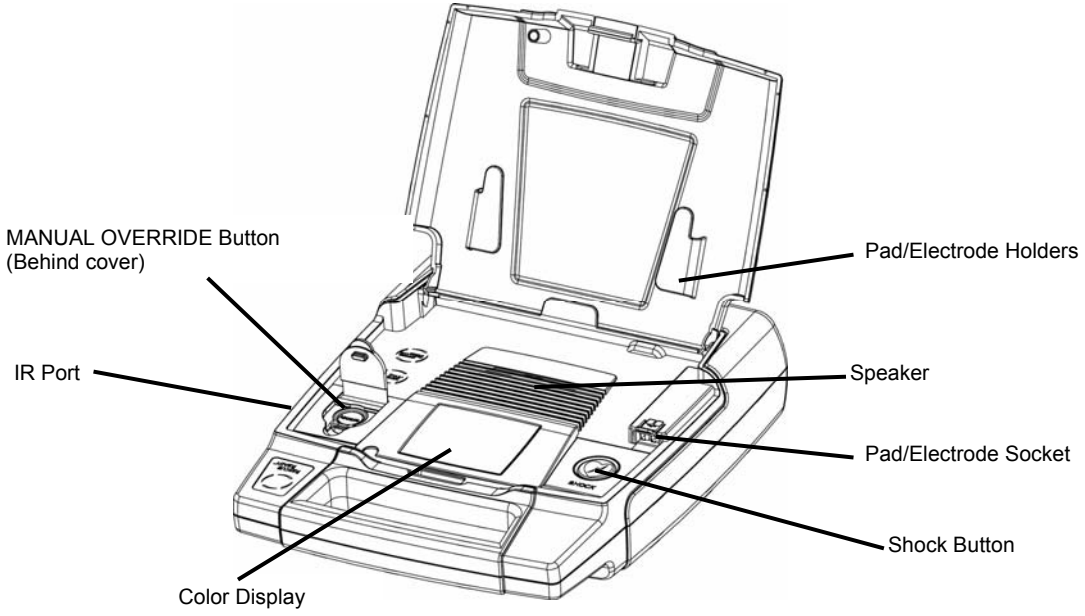
## AED PRO PARTS

The following drawings show the AED Pro parts and their locations.




### THE AED PRO HAS THREE MODES:

**Operating Mode:** Defined as having the battery installed and the lid open. This is the mode the AED Pro would be in during an actual rescue situation.

**Standby Mode:** When the battery is installed, but the lid is closed. In this mode the AED Pro is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

**Storage Mode:** When the battery is removed, such as during shipping or transport. With the battery removed, the AED Pro is unable to perform self-tests or rescues.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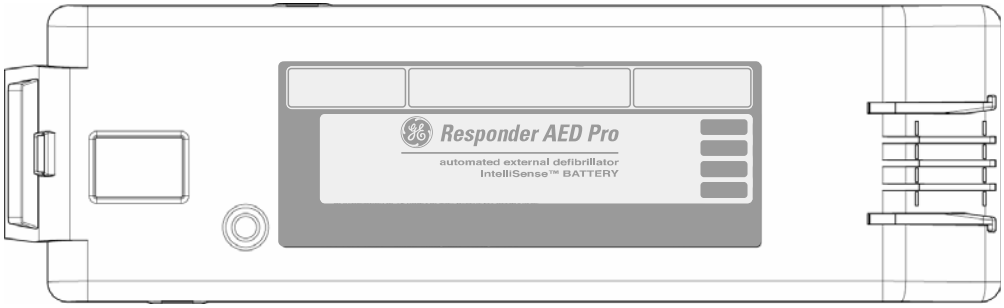
# INTELLISENSE® BATTERY




## ABOUT THE INTELLISENSE® BATTERY

- When the last battery indicator (LED) is red, the battery is low. Replace the battery right away.
- A new battery typically takes 10 seconds to charge the AED Pro to maximum energy.
- AED Pro batteries will provide up to 290 shocks
- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

| MODEL | TYPICAL SHOCKS |
|---|---|
| 2023681 (9145) Lithium | Up to 290 |

## BATTERY SHELF LIFE

The Responder AED Pro batteries have a shelf life of five years. Shelf life is defined as the length of time a battery can be stored, prior to installation into AED Pro, without degrading its performance.

***Note:*** Storing the battery outside its specific range (0-50°C)(30-122°F) will decrease battery life.

***WARNING:*** Lithium Sulfur Dioxide Battery 2023681-001 (9145) is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

***CAUTION:*** Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

***CAUTION:*** Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

***CAUTION:*** Use only Manufacturer Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the Responder AED Pro to function improperly during a rescue.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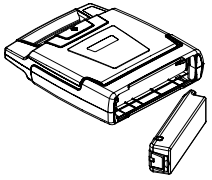
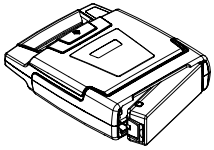
## BATTERY INSTALLATION



1. With the label on the battery facing the AED Pro battery compartment, insert the battery as shown in the drawing.



2. Push the latched end of the battery firmly into the AED Pro, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED Pro case.

3. Open the lid for 5 seconds to initiate self-test. If the battery is installed properly, the STATUS INDICATOR will turn GREEN. Close the lid.

***Note:*** Batteries with part number 2023489-001 (9144) and 2023681-001 (9145) are for use only with Responder AED Pro and should not be used with other AEDs.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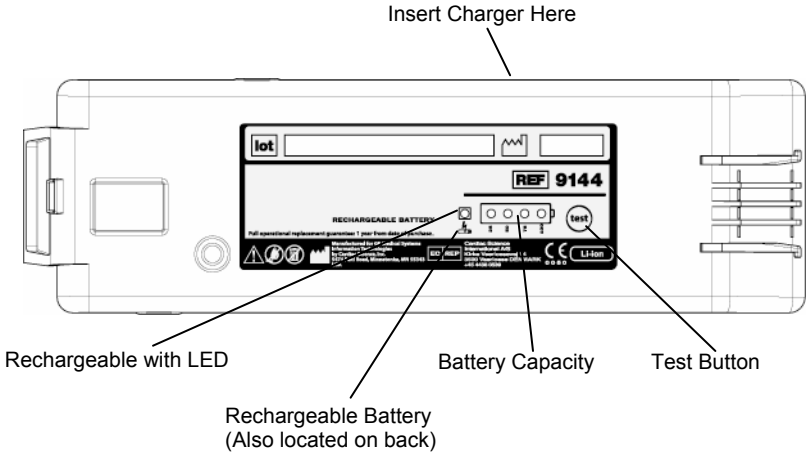
# RECHARGEABLE BATTERY

The rechargeable battery (P/N 2023489-001) and charger (P/N 2023490-001) are separately sold accessories for the Responder AED Pro.

## DIRECTIONS FOR USE:

- Remove the rechargeable battery from the Responder AED Pro; the rechargeable battery can only be recharged when removed from the Responder AED Pro.
- Plug the charger into an appropriate electrical outlet.
- Insert the charger cable into the rechargeable battery and ensure the yellow LED above the rechargeable battery symbol is on. Charging is complete when the yellow Charge LED goes out, and the four green Fuel Gauge LEDs are continuously lit.
- Remove the charger cable from the battery when done charging. Charging may be terminated early by removing the charger cable from the battery. If the battery is charged for a minimum of 3 hours, the stated capacities will be met.

If the yellow Charge LED blinks continuously, a charging error has occurred. Contact customer service in the event of a charging error.





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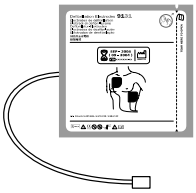
# DEFIBRILLATION ELECTRODES (PADS)



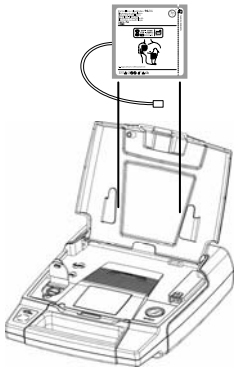
The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue. The pads have a limited shelf life and shall not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED Pro at all times. Refer to the pads package label for operation temperatures.

An audible and visual alert will indicate after the self-test if the pads are missing, unplugged or damaged.

***CAUTION:*** Damaged or Expired Pads

Using pads that are damaged or expired may result in improper AED Pro performance.

## PAD INSTALLATION



1. Open the lid of the AED Pro.
2. Place the pad package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the pads will then be readable without opening the lid of the AED Pro.
3. Match the color of the connectors (red to red), slightly lift the tab of the pad socket then plug the pad connector into the AED Pro case as shown in the drawing.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the pad package completely secured to the AED Pro lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid.
6. Make sure that the **STATUS INDICATOR** is **GREEN**.

***CAUTION:*** Use only Approved Equipment
Using batteries, defibrillation pads, cables, or optional equipment other than those approved by General Electric may cause the AED Pro to function improperly during a rescue.

***CAUTION:*** Possible Improper AED Pro Performance
Using defibrillation pads that are damaged or expired may result in improper AED Pro performance.

***CAUTION:*** Both polarized and non-polarized defibrillation pads are available for Responder AED Pro. If using polarized pads, always place sternum and apex pads as shown on the packaging. Non-polarized pads may be placed in either position for a rescue; however, the ECG waveform will be correctly displayed in only one position. To correctly display an inverted ECG, simply reverse the defibrillation pads.

## DIRECTIONS FOR USE:

1. Do NOT open until ready to use, short term use only.
2. Ensure the skin site is clean and dry.
3. Separate one pad from liner.
4. Place one pad on skin.
5. Peel and place remaining pad.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# AED PRO INDICATORS

The following indicators are located on the AED Pro.

## RESCUEREADY® STATUS INDICATOR

The **STATUS INDICATOR** is located on the Responder AED Pro handle. When this indicator is **GREEN**, the device is RescueReady. This means the AED Pro self-tests have verified the following:

- Battery has an adequate charge.
- Pads are properly connected to the AED Pro and in working order.
- Integrity of the internal circuitry is good.

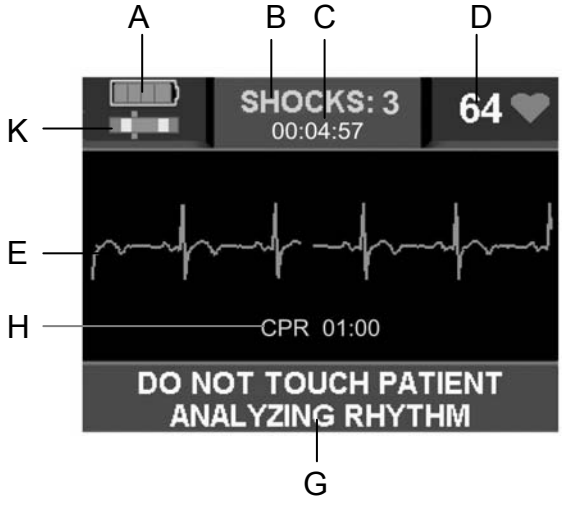
When the **STATUS INDICATOR** is **RED**, maintenance is required.

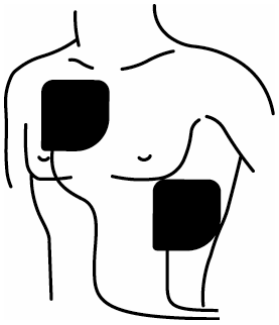
***Note:*** When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

## AUDIBLE MAINTENANCE INDICATOR

When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the next automatic self-test does not correct the error, the beep will be reactivated.

## DIAGNOSTIC PANEL



**A. SMARTGAUGE BATTERY Indicator**

This indicator displays the battery capacity. At maximum charge, the battery is GREEN. With use, the GREEN level will gradually go out from right to left as the battery capacity decreases. Once the battery level is depleted, the battery indicator will turn to RED and flash, and the battery should be replaced.

***Note***: When the battery indicator is RED, upon lid opening or at any time during the rescue – a "BATTERY LOW" prompt will be issued at once. However, the AED Pro is capable of delivering at least nine more defibrillation shocks after the first time a "BATTERY LOW" prompt is issued.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**B. NUMBER OF SHOCKS DELIVERED Indicator**
This indicator counts and displays the number of shocks delivered.

**C. ELAPSED RESCUE TIME Indicator**
This indicator times and displays the elapsed rescue time.

***Note:*** There is a 3 second delay between the time the AED Pro lid is opened and the start of the rescue (when the lid was first opened).

**D. HEART RATE Indicator**
This indicator displays the patient's heart rate.

**E. ECG Display**
Four and a half seconds of the patient's ECG is displayed.

**F. PAD PLACEMENT Display**
Visually assists the operator with pad placement with the directions for use. Appropriate text prompts are also displayed.

**G. TEXT Display**
The text display has 2 lines of text. It provides the operator with information regarding system initialization, text version of the voice prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions.

**H. CPR Counter**
During CPR, a countdown timer will be displayed.

**I. SERVICE Indicator**
When displayed, indicates that service is required that can only be performed by qualified service personnel.

***Note:*** When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

**J. PAD Indicator**
The pad indicator will flash with a voice and text prompt indication "Check Pads" when one of the following occurs:

- Pads are not properly connected to the AED Pro
- Pads are not within operational specifications (cold, dried, damaged)
- Pads are not connected properly to the patient during the rescue.

**K. Z-BAR Indicator**
The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of:

- Adequate pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper pad connection to the AED Pro
- Provides for quick assessment between pad off and pads shorted


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## CONTROL BUTTONS

The AED Pro has two buttons.

### SHOCK BUTTON

The SHOCK button is located at the far right of the control panel and serves as an indicator to notify the user that the unit is ready to shock and as a button to deliver the shock.

The word SHOCK and the shock button will illuminate RED when the AED Pro is ready to deliver a defibrillation shock to the patient.

### MANUAL OVERRIDE BUTTON

The MANUAL OVERRIDE button is located at the far left of the control panel and converts the device from automated mode to manual. This feature should only be used by medical professionals trained in manual defibrillation.

### MANUAL OVERRIDE

- Lift the cover to access the button.
- Converts to manual standby mode when pushed once, a voice prompt "*Press Manual Button Again to Confirm*", will be heard. Converts to manual mode when MANUAL button is pressed again.
- If the rescuer does not confirm within 30 seconds of the capacitors charging, the AED will revert back to AED Mode.
- If the Medical Director has disabled this feature in MDLink, an icon indicating No MANUAL MODE will appear in the bottom left of the display

# SETTING THE AED PRO INTERNAL CLOCK

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. The AED Pro will automatically adjust itself for daylight savings time. This feature can be turned off using the ServiceLink software. To set the clock, you will need a PC with Windows 95 or later operating system, RescueLink software installed, an IR port on the PC, and an IR adapter as specified below.

To set the clock settings:

- Open the lid and remove pads from the pads socket.
- Ensure that the PC is set at the correct local time and date.
- Point IR port on the AED Pro to IR eye on the PC and select G3 Pro.
- Run the RescueLink software on the PC.
- Verify that the voice prompt states "Communications Mode".
- Click Communications on the main menu. Select AED Pro Date and Time.
- Click on the Get button to review the current time in the AED Pro.
- If the time and date is incorrect, click Set to set new time and date. The AED Pro date and time will automatically be updated to the PC's time and date.
- Reinstall pads per instructions on page 18.
- Close the lid.

***Note:*** The IR port on the AED Pro is designed to work with IR adapter ACT-IR220LN115 from ACTiSys Corp. on Windows based PCs only. Please contact customer service to order, P/N 162-0108-001. Other IR products may interfere with the transmission and are not for use with the AED Pro.


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## VOICE PROMPTS AND TEXT DISPLAY

The voice prompts activate when the AED Pro lid is opened and help guide the operator through the rescue. The Responder AED Pro text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| "Tear Open Package and Remove Pads." | TEAR OPEN PACKAGE<br>REMOVE PADS | When the lid is opened, this phrase is repeated twice to initiate the rescue sequence. |
| "Peel One Pad from Plastic Liner." | PEEL ONE PAD<br>FROM PLASTIC LINER | Prompt repeats until one pad is peeled off of the liner. |
| "Place One Pad on Bare Upper Chest." | PLACE ONE PAD ON<br>BARE UPPER CHEST | Prompt repeats twice while one pad is placed. |
| "Peel Second Pad and Place on Bare Lower Chest as Shown." | PEEL SECOND PAD<br>PLACE ON LOWER CHEST | Prompt repeats until both pads are placed on the patient. |
| "Press Pads Firmly to Patient's Bare Skin." | PRESS PADS TO<br>PATIENT'S BARE SKIN | Prompt issued when better connectivity is required because impedance is too high. |
| "Do Not Touch Patient! Analyzing Rhythm." | DO NOT TOUCH PATIENT<br>ANALYZING RHYTHM | Prompt issued when the AED Pro is analyzing the cardiac rhythm of the patient. |
| "Shock Advised." | SHOCK ADVISED | Prompts issued when the AED Pro is preparing to deliver a defibrillation shock. |
| "Charging." | CHARGING | Prompt repeats while AED Pro is charging. |
| "Stand Clear! Push Flashing Button to Deliver Shock." | STAND CLEAR<br>PUSH BUTTON TO SHOCK | Prompt issued after the AED Pro is fully charged and ready to deliver the defibrillation shock. The RED Shock indicator flashes and the phrase repeats for 30 seconds or until the Shock button is pushed. |
| "Plug in Pads Connector" | PLUG IN PADS<br>CONNECTOR | Prompt issued when the pad socket does not have defibrillation pads or ECG electrodes connected. |
| "Shock Delivered" | SHOCK DELIVERED | After the AED delivers a defibrillation shock |
| "It is now safe to touch the patient" | NOW SAFE TO TOUCH THE PATIENT | Advises the rescuer when it is safe to touch the patient. |
| Start CPR | START CPR | After the AED delivers a defibrillation shock. After the AED detaches a non-shockable rhythm. |
| Give 30 compressions<br>Then Give Two Breaths | 30 COMPRESSIONS<br>2 BREATHS | Perform CPR for 2 minutes |


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## (VOICE PROMPT AND TEXT DISPLAY CONTINUED)

| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| "Check Pads" | CHECK PADS | Prompt issued when patient impedance is too low or the pads are shorted. |
| "Battery Low" | BATTERY LOW | Prompt issued once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the phrase repeats continuously. You must replace the battery before continuing with the rescue. If completely depleted, all AED Pro activity will terminate. |
| "Analysis Interrupted. Stop Patient Motion." | ANALYSIS INTERRUPTED<br>STOP PATIENT MOTION | Prompt issued when the AED Pro detects ECG noise artifact, stop moving or touching the patient. |
| "Open Lid to Continue Rescue" | OPEN LID TO<br>CONTINUE RESCUE | Prompt issued when the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds. |
| "Rhythm Changed.<br>Shock Cancelled." | RHYTHM CHANGED<br>SHOCK CANCELLED | Prompt issued when the device is prepared to shock then detects a change in rhythm and therefore cancels the shock. |
| "ECG Monitoring Mode" | ECG MONITORING MODE | Prompt issued when ECG Patient Cable is inserted into the pad socket. |
| "Communications Mode" | COMMUNICATIONS MODE | Prompt issued when the lid is open and IR is transmitting the AED Pro. |
| (Beep) | (None) | One "Beep" occurs in 30-second intervals during CPR when enabled by the ServiceLink software program, also occurs when the AED Pro requires maintenance. |
| "Continue CPR" | CONTINUE CPR | Prompt issued during CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing. |
| "Service Required" | SERVICE REQUIRED | Prompt issued after the self-tests determine that the AED Pro is not functioning properly. The prompt "Service Required" will be heard when the lid is opened. The red Service indicator will illuminate and "Service Required" will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted. |


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## ADVANCED FEATURE PROMPTS

| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| "Entering Manual Mode. Press Button Again to Confirm" | MANUAL MODE<br>PRESS BUTTON TO CONFIRM | Prompt issued after ALS presses the MANUAL button once to initiate the manual mode. |
| "Manual Mode. Charging" | MANUAL MODE<br>CHARGING | Prompt issued after ALS presses the MANUAL button again to confirm. |
| "Manual Mode Not Confirmed." | MANUAL MODE<br>NOT CONFIRMED | Prompt issued when the MANUAL button is not pressed a second time within five seconds, the device stays in AED Pro mode. |
| "If Rhythm is Shockable, Press SHOCK Button to Deliver Therapy." | IF SHOCKABLE RHYTHM<br>PRESS SHOCK BUTTON | Prompt issued when in manual mode, prompts ALS personnel to press SHOCK button if ECG indicates a shockable rhythm. |
| "Shockable Rhythm. Attach Defibrillation Pads." | SHOCKABLE RHYTHM<br>ATTACH DEFIBRILLATION PADS | Prompt issued when the device is performing ongoing ECG monitoring via the ECG Patient Cable Kit and detects a shockable rhythm. |
| "Device Will Disarm in :30" | DEVICE WILL DISARM IN :30 | Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED Pro will revert back to AED mode 30 seconds after charging is complete. The seconds will count down from 30 on the display.<br>When "Remain in manual mode" has been enabled (Using ServiceLink software). The AED will disarm but remain in Manual Mode. See page 27 |


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# SECTION 3: PERFORMING A RESCUE

## OVERVIEW

The AED Pro is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.


| TOPIC | PAGE # |
|---|---|
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| HOW TO PERFORM A RESCUE | 24 |
| USING MANUAL OVERRIDE | 27 |
| Z-BAR INDICATOR | 29 |
| WARNINGS | 30 |


## OPERATING MODES

The AED Pro comes in three operating models. The AED Pro is pre-set to AED mode, but the user can change the mode during each unique rescue. The energy delivered is determined by the Medical Director and programmed into the AED Pro prior to the rescue.

### AED MODE (default)

For patients exhibiting signs of sudden cardiac arrest. Once defibrillation pads are placed on the patient, the AED Pro analyzes the heart rhythm. If a shockable rhythm is detected, the AED Pro automatically charges to a pre-set energy level and prompts rescuer to push the SHOCK button to deliver therapy.

### MANUAL MODE

For patients exhibiting signs of sudden cardiac arrest. Once the defibrillation pads are placed on the patient, a trained ALS rescuer may wish to read the ECG display to determine whether or not a shock is required. This mode is activated by pushing the manual button once then again to confirm; the device will begin charging. If the rescuer deems that the rhythm is shockable, therapy can be delivered by pressing the SHOCK button. Then, the AED Pro reverts back to AED mode. By entering this mode, the rescuer is taking responsibility to identify a shockable rhythm and to administer a shock. Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED Pro will revert back to AED mode 30 seconds after charging is complete. The seconds will count down on the display. If the Medical Director has disabled this feature in ServiceLink, an icon indicating NO MANUAL MODE will appear in the bottom left of the display. With Manual Mode enabled and the Medical Director has also enabled "REMAIN IN MANUAL MODE" the AED will not revert to the AED or CPR mode, but will remain in Manual mode

### ECG DISPLAY MODE

For patients who are conscious and breathing for longer term ECG monitoring. ECG display fur use in determining gross morphology can be activated by inserting the ECG patient monitoring cable into the electrode socket on the AED Pro, connecting the 3-lead patient cables to the specialized ECG electrodes and placing as directed onto the patient. Should the AED Pro detect a shockable rhythm, defibrillation pads should be placed on the patient, the ECG patient monitoring cable removed from the electrode socket on the AED Pro and the connector should be plugged into the pad socket to enable a defibrillation shock.


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# HOW TO PERFORM A RESCUE

## STEP 1: ASSESSMENT AND PAD PLACEMENT

### PREPARATION

Determine that the patient is over 8 years of age or weighs more than 55 pounds (25 kg) and exhibits the following:

The patient is unresponsive, and
The patient is not breathing.

Perform CPR until AED is attached to patient.

Remove clothing from the patient's chest. Ensure the skin site is clean and dry. Dry the patient's chest and shave excessive hair if necessary.

Open the AED lid and follow prompts.

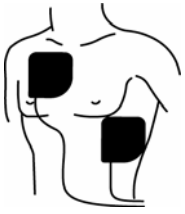
***Warning*:** When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 2019199-003 Pediatric Attenuated Defibrillation Electrodes. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric electrodes for procedure on changing adult pads to pediatric.

***Note:*** When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

### PLACE PADS

The AED will issue the prompt "Tear Open Package and Remove Pads." Keep the pads connected to the AED, tear the package along the dotted line and remove the pads from the package. Leave the package attached to the pad wires.

After the prompt "Peel One Pad From Plastic Liner," with a firm, steady pull, carefully peel one pad away from the release liner.



Then, after the prompt "Place One Pad on Bare Upper Chest," place the pad with the sticky side of on the patient's skin on the upper right chest, placing the top of the pad on the collarbone. Avoid placing the pad directly over the sternum.

Finally, after the prompt "Peel Second Pad and Place on Bare Lower Chest As Shown," pull the second pad from the release liner and place it on the lower left chest, below and left of the breast.

***Note:*** The standard defibrillation pads are non-polarized and can be placed in either position as shown on the pad package. When using pacing or monitoring pads, refer to placement instructions on the pacing or monitoring pad package.

When the pads are placed, the voice prompt will say "Do not touch patient. Analyzing Rhythm." If the pads are not properly placed or become disconnected at any time during the rescue, the voice prompt "Check Pads" will be heard. When this occurs, ensure that:

Pads are firmly placed on clean, dry skin
Pads cable is securely plugged into the AED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## STEP 2: ECG ANALYSIS (AED MODE)

As soon as the AED detects proper pad placement, the voice prompt “Do not touch patient. Analyzing Rhythm.” will be heard. The AED will begin to analyze the cardiac rhythm of the patient.

If a shock is advised, the voice prompt will say, “Shock Advised. Charging.” When the AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt, “Stand Clear. Push Flashing Button to Deliver Shock” will be heard. The tone, flashing button, and voice prompt will continue until the shock is delivered or change in rhythm is detected, or 30 seconds elapse.

When the AED is charged, it continues to analyze the patient’s heart rhythm. If the rhythm changes and a shock is no longer needed, the AED will issue the prompt “Rhythm Changed. Shock Cancelled,” disarm and enter CPR mode.

If noise is detected during analysis, the AED will warn you with the prompt “Analysis Interrupted. Stop Patient Motion” and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 2 meters). Remove the electronic device or stop the excessive motion when you hear this prompt.

## STEP 3: SHOCK DELIVERY AND CPR MODE (AED MODE)

When the AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt “Stand Clear. Push Flashing Button to Deliver Shock” will be heard.

Make sure no one is touching the patient and push the Shock button to deliver a defibrillation shock. If you do not push the Shock button within 30 seconds of hearing the prompt, the AED will disarm and enter CPR mode.

After the AED delivers the first defibrillation shock, the voice prompt will say “Shock Delivered.” The AED will then prompt you to start CPR.

***Note:*** During a rescue, the screen displays voice prompts, elapsed time of rescue and number of shocks delivered.


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## CPR MODE

After shock delivery or detection of a non-shockable rhythm, the AED automatically enters CPR mode. The voice prompt will say, “It is now safe to touch the patient. Start CPR.”

During the CPR time-out period, the AED will not interrupt the CPR mode. After the CPR time-out period has expired, the voice prompt “Do Not Touch Patient. Analyzing Rhythm.” will be heard.

***Note:*** During CPR mode, a countdown timer is displayed.

If the patient is conscious and breathing normally, leave the pads on the patient’s chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support [ALS] personnel to arrive. Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director.

## STEP 4: POST RESCUE

After transferring the patient to ALS personnel, prepare the AED for the next rescue:

1. Retrieve the rescue data stored in the internal memory of the AED by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Connect a new pair of pads to the AED.
3. Close the lid.
4. Verify that the Status Indicator on the AED handle is GREEN.


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## USING MANUAL OVERRIDE (manual mode)

For use by qualified ALS personnel only. The AED Pro has a manual override feature which overrides the AED Pro's automatic analysis protocol. By entering this mode, the rescuer is taking responsibility to identify a shockable rhythm and to administer a shock. The default setting for the manual override is "enabled". When enabled, the Manual Override option allows the user to charge the AED and deliver a shock at the user's discretion. After the shock button is pushed or 30 seconds has elapsed, the device will automatically exit the manual mode and return to the AED mode.

Optionally, the manual override default behavior may be modified so that after entering manual mode, the AED will remain in the manual override mode for the duration of the rescue. This feature is enabled by selecting the "REMAIN IN MANUAL MODE" option in the ServiceLink software and can be configured during the initial set up of the AED.

STEP 1: Please refer to: "STEP 1: ASSESSMENT AND PAD PLACEMENT" on page 24.

STEP 2: Lift plastic cover on far left of diagnostic panel.

STEP 3: Push the MANUAL button once to initiate. The voice prompt and corresponding text prompts will indicate "Entering manual mode. Press button again to confirm."

STEP 4: The MANUAL button must be pushed again to confirm and convert to manual mode. The manual indicator on the display panel will be active. The voice and corresponding text prompts will indicate, "Manual Mode."

***Note:*** The manual mode is initially displayed on the screen when activated. If the Medical Director has disabled this feature in ServiceLink, an icon indicating NO MANUAL MODE will appear in the bottom left of the display. Continue the rescue in AED Mode.

STEP 5: The voice prompts and corresponding text prompts will indicate, "If rhythm is shockable, press SHOCK button to deliver therapy". Read the ECG and determine if the rhythm is shockable. If so, press the SHOCK button to delivery therapy.

***Note:*** The RHYTHMx analysis algorithm is disabled in manual mode. It is the rescuer's responsibility to determine if a shock is necessary

STEP 6: The AED Pro will revert to AED / CPR MODE once a shock is delivered. Follow the voice prompts. If "Remain in Manual Mode" has been enabled, the device will remain in Manual Mode.

STEP 7: To re-enter manual mode, press the MANUAL button ONCE.

***Note****:* Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED Pro will revert back to AED mode 30 seconds after charging is complete. The seconds will count down on the display. If "Remain in Manual Mode" has been enabled, the device will remain in Manual Mode.

### EXITING MANUAL MODE

Default: The device will return to AED mode after:

- Pushing the shock button
- 30 seconds has elapsed without pushing the shock button
- Closing the AED lid momentarily
- Removing the battery momentarily
- Attaching the optional 3-lead ECG monitoring cable
- Disconnecting the pads from the AED
- Removing the pads from the patient

### EXITING MANUAL MODE WHEN "REMAIN IN MANUAL MODE" HAS BEEN ENABLED

- Closing the AED lid momentarily
- Removing the battery momentarily
- Attaching the optional 3-lead ECG monitoring cable (upon reattaching the defibrillation pads the AED will be in manual mode).

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## ECG DISPLAY USING SEPARATE ECG LEAD WIRES (ECG DISPLAY MODE)

The AED Pro can be used for ongoing display of ECG for attended monitoring of gross morphology. This feature requires a separately sold ECG Patient Cable Kit. It is not necessary to turn the device off prior to connecting the ECG cable. While the ECG cable is connected to the AED Pro, the shock capability is disabled.

**Indications for use:**
A conscious or breathing patient, regardless of age.

**Contraindications:**
No known contraindications.

The separately sold ECG Patient Cable Kit is required to use this feature. The Kit is designed for connection to ECG electrodes per AAMI or IEC color convention. Once connected the AED Pro displays and evaluates the patient's ECG (Lead II). Follow all prompts from the AED Pro.

The kit includes a device connector, which contains electronics (with a non-replaceable battery) that is inserted into the pad port on the AED Pro, a trunk cable terminating in a molded yoke and three patient leadwires permanently attached to the yoke. Each leadwire terminates in an electrode connector to attach to a disposable pad

***CAUTION:*** Not a Patient Monitor
**The AED Pro is not a true patient monitor with the requisite alarms. Medical personnel should attend patients at all times while the AED Pro is in use.**


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# Z-BAR™ INDICATOR

The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of:

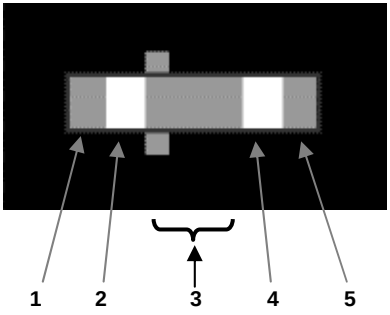
- Adequate Pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper Pad connection to the AED Pro
- Provides for quick assessment between PADS OFF and PADS SHORTED

***Note:*** The Z-Bar is displayed on all therapy screens with the exception of the ECG MONITORING screen. On the ECG MONITORING screen the Z-Bar will be displayed only if the detection lead is set to Pads.

The Z-Bar is divided into 5 sections. The ideal operating range is Section 3 (impedance range from 30 to <150).

**Z-BAR**

| SECTION | MEASURED IMPEDANCE RANGE (OHMS) | DESCRIPTION | COLOR FILL |
|---|---|---|---|
| 1 | <20Ω | Lower Limit Alarm – Non operational range | Red |
| 2 | >20 but < 30Ω | Lower marginal operating range. Indicates potential Pad degradation in Pad quality or position | Yellow |
| 3 | >30 but < 150Ω | Normal operating range | Green |
| 4 | >150 but <180Ω | Upper marginal operating range. Indicates potential Pad degradation in Pad quality or position | Yellow |
| 5 | >180Ω | Upper Limit Alarm – Non operational range | Red |





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## WARNINGS

The following cautions must be observed to prevent problems during the rescue.

***DANGER:*** Fire and Explosion Hazard
Do not use in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

***WARNING:*** Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Do not use in water
- Keep defibrillation pads and ECG electrodes clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

***WARNING***: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

***CAUTION:*** Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the AED Pro to function improperly during a rescue.

***CAUTION:*** Possible Improper AED Pro Performance
Using pads that are damaged or expired may result in improper AED Pro performance.

***CAUTION***: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED Pro, do not operate wireless radiotelephones within 2 meters of the AED Pro – turn power OFF to the radiotelephone and other like equipment near the incident.

***CAUTION:*** Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED Pro has pacemaker detection and rejection, however with some pacemakers the AED Pro may not advise a defibrillation shock.

Placing Pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least on inch from any implanted device.

***CAUTION***: Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause the AED Pros to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.


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# SECTION 4: DATA MANAGEMENT

## OVERVIEW

The Responder AED Pro is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.


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| REVIEW THE RESCUE DATA | 31 |
| RESCUELINK OVERVIEW | 32 |
| RESCUELINK INSTALLATION INSTRUCTIONS | 33 |
| MULTIPLE RESCUE FUNCTIONALITY | 33 |


## RECORDING THE RESCUE DATA

### RECORDING DATA IN INTERNAL MEMORY

The AED Pro automatically stores up to 60 minutes of the latest rescue data.

## REVIEWING THE RESCUE DATA

### RETRIEVING DATA FROM MEMORY

1. Open the AED Pro lid and remove pads from socket.
2. Point IR port on the AED Pro to IR adapter attached to the PC.
3. Run the RescueLink software program on the PC and select G3 Pro.
4. Select Communications, Get Rescue Data. On the RescueLink software program.
5. The voice prompt will say “COMMUNICATIONS MODE”.
6. Select Internal Memory of AED then select OK.
7. Reinstall pads and close lid.

***Note:*** The approved IR adapter is ACT-IR220LN115 from ACTiSYS Corp. Please contact customer service to order.


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## RESCUELINK OVERVIEW

RescueLink® software application is used for transferring, viewing, and storing rescue data recorded by an automated external defibrillator.

***Note:*** Rescue data managed by RescueLink is for archival purposes only. RescueLink does not attempt to interpret medical information and is not a medical device.
RescueLink allows you to manage rescue data retrieved from the AED by transferring rescue data from the AED to a computer.

The computer may then be used to:
• View, print and store rescue data
• Display and set the AED date and time
• Clear rescue data from the AED

RescueLink is programmed with on-line Help. Help may be accessed by selecting *Help, Search for Help on….* from the menu bar.

### RESCUELINK SOFTWARE PC REQUIREMENTS

The following is a list of minimum requirements need to install the RescueLink software.

| TYPE | SPECIFIC |
|---|---|
| Processor | 486SX - 66MHz |
| RAM | 16 Megabytes |
| Hard Drive | 20 Megabytes free space |
| Operating System | Windows 95<br>Windows 98<br>Windows 2000<br>Windows XP |
| Communications Port | COM 1 |
| Printer Port | LPT1 or network printer |
| PCMCIA card reader | Type I or Type II PCMCIA Card Reader |
| Sound | Sound Blaster Compatible Audio Card with Stereo Speakers |
| Screen Area | 600 X 800 pixels |
| Mouse | Windows compatible |
| Printer | Windows compatible |
| Keyboard | Windows compatible |
| CD-ROM | Windows compatible |


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## RESCUELINK INSTALLATION INSTRUCTIONS

***Note:*** You will need administrator privileges to install the RescueLink software application.

To install RescueLink, follow these steps:

1. Verify your computer meets the minimum requirements as defined in *RescueLink Software PC Requirements* section of this manual.
2. Quit all programs and insert the RescueLink CD into your CD ROM drive.
3. The installation routine will start automatically after inserting the CD.
   If the installation routine does not start automatically, run the setup.exe file from the CD.
4. Choose your language and Click OK. The program will automatically default to the operating system language on your computer.
5. The installation program will guide you through the installation process.
6. After successful installation, you will be able to run RescueLink by:
   a. Selecting *Start, All Programs*, Cardiac Science Corp, RescueLink; or
   b. Clicking on the RescueLink icon on your computer's desktop
   c. Simultaneously selecting Ctrl +Alt +R on your keyboard

## MULTIPLE RESCUE FUNCTIONALITY

The AED Pro can store up to 60 minutes of ECG monitoring time in the AED Pro's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED Pro will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application HELP files for more information.


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# SECTION 5: MAINTENANCE & TROUBLESHOOTING

## OVERVIEW

This section presents information about the AED Pro diagnostics self-tests, maintenance, and service indications.


| TOPIC | PAGE # |
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| SELF TESTS | 35 |
| INDICATOR TROUBLESHOOTING TABLE | 36 |
| SCHEDULED MAINTENANCE | 36 |
| AUTHORIZED REPAIR SERVICE | 37 |
| FREQUENTLY ASKED QUESTIONS | 38 |


## SELF-TESTS

The AED Pro has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED Pro lid.

When performing the self-tests, the AED Pro completes the following steps automatically.

- Turns itself ON, and the **STATUS INDICATOR** changes to **RED**.
- Performs the self-test.
- If successful, the **STATUS INDICATOR** reverts to **GREEN**.
- Turns itself OFF if the lid is closed.

There are three types of automatic self-tests. The Daily Self-Test checks the battery, pads, and the electronic components. The Weekly Self-Test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-Test. During the Monthly Self-Test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the **STATUS INDICATOR** will remain **RED**. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

***CAUTION:*** Temperature/Humidity/Pressure Extremes
Exposing the AED Pro to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED Pro to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED Pro; if the daily self test determines environmental conditions outside of the AED Pro's operating parameters, the "SERVICE REQUIRED" alarm will sound to alert the user to move the AED Pro to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.


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## INDICATOR TROUBLESHOOTING TABLE

The following is a troubleshooting table for the AED Pro indicators.

| VIEW | SYMPTOM | SOLUTION |
|---|---|---|
| | Red **SERVICE** indicator (LED) is indicated on the screen. | Maintenance by authorized service personnel is required. Call Customer Service or your local distributor. |
| | Red **PADS** indicator (LED) is indicated on the screen. | Connect the pads or replace with a new pair. |
| | The **SMARTGAUGE BATTERY** indicator shows one bar of battery life that is red and flashing. | The battery is low. Replace with a new battery. |
| | **STATUS INDICATOR** is **RED**, and no other indicators on the diagnostic panel are lit. | The battery power is completely depleted. Replace with a new battery. If **STATUS INDICATOR** remains **RED**, refer to the Responder AED Pro for maintenance. Call Customer Service or your local distributor. |

## SCHEDULED MAINTENANCE

### DAILY MAINTENANCE

Check the **STATUS INDICATOR** to ensure that it is **GREEN**. When the indicator is **GREEN**, the Responder AED Pro is ready for a rescue. If the indicator is **RED**, refer to the Troubleshooting Table in this chapter.

### MONTHLY MAINTENANCE

1. Open the AED Pro lid.
2. Wait for the AED Pro to indicate status
   Observe the change of the **STATUS INDICATOR** to **RED**. After approximately 5 seconds, verify that the **STATUS INDICATOR** returns to **GREEN**.
3. Check the expiration date on the pads.
4. Listen for the voice prompts.
5. Close the lid and confirm that **STATUS INDICATOR** remains **GREEN**.


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## ANNUAL MAINTENANCE

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

**Check the Integrity of the Pads and Circuitry**

1. Open the AED Pro lid.
2. Remove the pads.
3. Close the lid.
4. Confirm that the **STATUS INDICATOR** turns **RED**.
5. Open the lid and confirm that the **PAD** indicator is lit.
6. Reconnect the pads and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid.
8. Check to make sure that the **STATUS INDICATOR** is **GREEN**.
9. Open the lid and confirm that no diagnostic indicators are lit.
10. Check the expiration date of the pads; if expired, replace them.
11. Check the pad's packaging integrity.
12. Close the lid.

**Check the Integrity of the Service Indicator (LED) and Circuitry**

1. Immediately after opening the AED Pro lid, press and hold the **SHOCK** button and confirm that the **SERVICE** LED is lit.
2. Release the **SHOCK** button.
3. **Close the lid.**
4. Verify that the **STATUS INDICATOR** remains RED.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.
7. Verify the **STATUS INDICATOR** turns GREEN

**Check the Integrity of the Case**

Examine the molded case of the AED Pro for any visible signs of stress. If the case shows signs of stress, contact Customer Service or contact your local distributor.

**Cleaning the AED Pro Case**

Gently clean the surface of the AED Pro case with a damp sponge or with a cloth and mild soap.

***CAUTION:*** Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

No periodic safety analysis tests referred to by the IEC 60601-1 international standard are required.

# AUTHORIZED REPAIR SERVICE

The AED Pro has no user-serviceable internal components. Try to resolve any maintenance issues with the AED Pro by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Customer Service.

***WARNING:*** Shock Hazard
Do not disassemble the AED Pro! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

***Note:*** The warranty will be void upon unauthorized disassembly or service of the AED Pro.


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# FREQUENTLY ASKED QUESTIONS

## QUESTIONS AND ANSWERS

1. Q: *Can I give CPR while the AED Pro is analyzing?*
   A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

2. Q: *Can I transport the victim while the AED Pro is analyzing?*
   A: No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

3. Q: *Do I need to prepare the chest prior to pad application?*
   A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. In some cases, the chest may need to be shaved. Follow your Medical Director's instruction.

4. Q: *What happens if the battery is low when I begin a rescue?*
   A: When the **BATTERY INDICATOR** is **RED**, the AED Pro issues a "*Battery Low*" prompt once; however, the AED Pro is still capable of delivering approximately 9 more defibrillation shocks.

   When the AED Pro is not capable of delivering any more shocks, it beeps once every 30 seconds. To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED Pro will begin to record the events from then on as a separate rescue.

5. Q: *How do I set the AED Pro internal clock?*
   A: Set the clock by using the RescueLink Software Program, PC and IR Adapter. See Setting the AED Pro Internal Clock.

6. Q: *What happens if I close the lid in the middle of a rescue attempt?*
   A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, "*Open lid to continue Rescue*." If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened. If the "remain in manual mode" option has been selected in the initial set up and the AED is in manual mode when the lid is momentarily closed and reopened, the AED will exit the manual mode and revert to the AED mode.

   ***Note:*** If the lid is closed during a rescue while the pads are connected to the patient, the **STATUS INDICATOR** may turn **RED**. When the lid is reopened, however, the rescue may be continued even though the **STATUS INDICATOR** remains **RED**.

7. Q: *My AED Pro is sounding an audible alert. Why? How do I stop it?*
   A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the **STATUS INDICATOR** will remain **RED**.

8. Q: *The AED Pro did not sound an audible alert when I removed the pads and closed the lid. Why?*
   A: The lid-closed pad self-test only activates the **STATUS INDICATOR**. The AED Pro allows time for replacement of the pads – as removing pads is a normal procedure after a rescue - or a battery during the post rescue procedure, however, an audible maintenance indicator will be triggered after the next Daily Self-Test.

9. Q: *What can I do to keep the AED Pro warm when a rescue is in an isolated area and at subzero temperatures?*
   A: When travel to a rescue involves exposing the AED Pro to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

10. Q: *What should I do if I initiate MANUAL MODE but then decide AED MODE is more appropriate?*
    A: Once charging is complete, wait 30 seconds for the AED Pro to revert back to AED MODE. The seconds will count down on the display. If "REMAIN IN MANUAL MODE" has been enabled, momentarily close the AED lid and reopen. The AED will then revert to AED mode.


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# SECTION 6: TECHNICAL DATA

## OVERVIEW

This section presents technical data about the AED Pro.


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| RHYTHMX AED ECG ANALYSIS ALGORITHM | 43 |
| STAR BIPHASIC WAVEFORM | 45 |
| STAR BIPHASIC ENERGY PROTOCOLS FOR RESPONDER AED PRO | 45 |
| ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS | 47 |


## PARAMETERS

### OPERATION

Semi-Automatic (shock advisory)
Manual

### AUDIBLE ALERTS

Voice Prompt
Maintenance Alert

### VISIBLE INDICATORS
### STATUS INDICATOR

Display Panel

BATTERY Indicator
NUMBER OF SHOCKS DELIVERED Indicator
ELAPSED RESCUE TIME Indicator
HEART RATE Indicator
ECG Display
PAD PLACEMENT Display, CHECK PADS indicator
TEXT Display
CPR Counter
SERVICE Indicator
Pad Indicator
Manual Mode Indicator
ECG Display Mode Indicator
Z-BAR Indicator


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## RESCUE DATA STORAGE

| Storage | Capacity |
|---|---|
| Internal | 60 minutes ECG data with event annotation |

## DIMENSIONS

| Measurement | Dimension |
|---|---|
| Height | 8 cm (3.3 in) |
| Width | 27 cm (10.6 in) |
| Depth | 31 cm (12.4 in) |

## WEIGHT

| Model | Weight with Batteries and Pads |
|---|---|
| 2023440 | 3.20 kg (7.0 lb) |

## ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

| Atmosphere | Condition |
|---|---|
| Temperature | 0°C to 50°C (32°F to 122°F) |
| Humidity | 5% to 95% (non-condensing) |
| Pressure | 57kPa (4,572m / +15,000ft) to 103kPa (-152m / -500ft) |

## SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

| Atmosphere | Condition |
|---|---|
| Temperature | -30°C to 65°C (-22°F to 149°F) |
| Humidity | 5% to 95% (non-condensing) |
| Pressure | 57kPa (4,572m / +15,000ft) to 103kPa (-152m / -500ft) |

***CAUTION:*** Cold Environments
If the AED Pro is stored in an environment with a temperature below the operating temperature, the unit should be allow to warm up to the needed operating temperature before using.


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## PADS (ADULT)

- Self-adhesive, disposable defibrillation pads
- Minimum combined surface area: 228cm$^2$
- Extended length of lead wire: 1.3m

## LITHIUM SULFUR DIOXIDE BATTERY SPECIFICATIONS

- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

| Model | Estimated Shelf Life | Warranty | Typical Shocks |
|---|---|---|---|
| 2023681 Lithium Sulfur Dioxide | 5 Years | 1 Year of 12 hours of use, whichever occurs first | Up to 290 shocks |

The battery operating life depends on the type of battery, actual usage and environmental factors.

## RECHARGEABLE BATTERY SPECIFICATIONS

- Battery Voltage: 11.1V
- Chemistry: Lithium-ion. Refer to local regulations.
- Compatibility: Responder AED Pro Model 2023440
- Battery Capacity: 60 shocks minimum (100 shocks typical) or 3 hours minimum (6 hours typical) of ECG display time.
- Battery Charge Time: 3 hours for stated capacity, 4.5 hours to fully charge completely depleted battery.
- Battery Standby: 6 months
- Battery Life: 2.5 years or 300 Battery charge-discharge cycles, whichever comes first.
- Battery Weight: .52kg (1 lb. 3 oz)

## BATTERY CHARGER

- Power Requirements: 90 to 132 VAC or 198 to 264 VAC at 47 to 63 Hz

The Charger operates from, and accepts standard IEC mains power cables.

It is recommended that you keep a spare, non-rechargeable battery nearby.


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## BATTERIES AND CAPACITOR CHARGE TIMES

A new battery typically takes 10 seconds to charge the AED Pro to maximum energy.

A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED Pro to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds for a new rescue.
The maximum time from “Analyze” to “Ready to Shock” is 22 seconds for a new rescue.

## AED Pro SELF-TEST SEQUENCE

| Frequency of Self-Test | What is Tested? |
|---|---|
| Daily | Battery, pads, internal electronics, **SHOCK** button, and software (no charge). |
| Weekly | Battery, pads, internal electronics, **SHOCK** button, and software (partial charge). |
| Monthly (every 28 days) | Battery under load, pads, internal electronics, full-energy charge cycle, **SHOCK** button, and software (full charge). |
| Open Lid (when lid is opened) | Battery, pads, internal electronics, **SHOCK** button, and software. |
| Close Lid (when lid is closed) | Battery, pads, internal electronics, **SHOCK** button, and software. |


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# RHYTHMX® AED ECG ANALYSIS ALGORITHM

The RHYTHMx AED ECG analysis algorithm provides superior ECG detection capabilities, allowing it to be placed on patients at risk for sudden cardiac arrest. The features available with the AED Pro include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

## DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is configurable between 120 bpm (beats per minute) and 240 bpm. Service can change this rate using the ServiceLink software. The default Detection Rate is 160 bpm. The Responder AED Pro detection rate is 160 bpm.

## ASYSTOLE THRESHOLD

The Asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as Asystole and will not be shockable.

## NOISE DETECTION

The AED Pro will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED Pro will issue the prompt "*ANALYSIS INTERRUPTED. STOP PATIENT MOTION*" to warn the operator. The AED Pro will then proceed to reanalyze the rhythm and continue with the rescue.

## NON-COMMITTED SHOCK

After the AED Pro advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED Pro will advise that the rhythm has changed and issue the prompt "*RHYTHM CHANGED. SHOCK CANCELLED*." The AED Pro will enter the CPR mode and prompt, "START CPR".

## SYNCHRONIZED SHOCK

The AED Pro is designed to synchronize shock delivery on the R-wave. The AED Pro will automatically attempt to synchronize to the R-wave. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

## PACEMAKER PULSE DETECTION

The AED Pro contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.


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## SVT (Superventricular Tachycardia) DISCRIMINATORS

The Responder AED Pro is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the Responder AED Pro will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT", however Service can change the settings for this feature using the ServiceLink software.

## SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable by Service between 160 and 300 bpm or, “NO THERAPY FOR SVT” can be selected by Service using the ServiceLink software.

## RESCUE PROTOCOL

The AED Pro rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1] European Resuscitation Council (ERC) and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the AED Pro advises the operator to press the SHOCK button to deliver a shock and then advises the operator to start CPR.

***Note:*** The standard CPR protocol of 120 seconds can be modified from 60 to 180 seconds in MDLink.

[1] “Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care” American Heart Association; Circulation Vol112,Issue 24 Suppl. Dec 13, 2005


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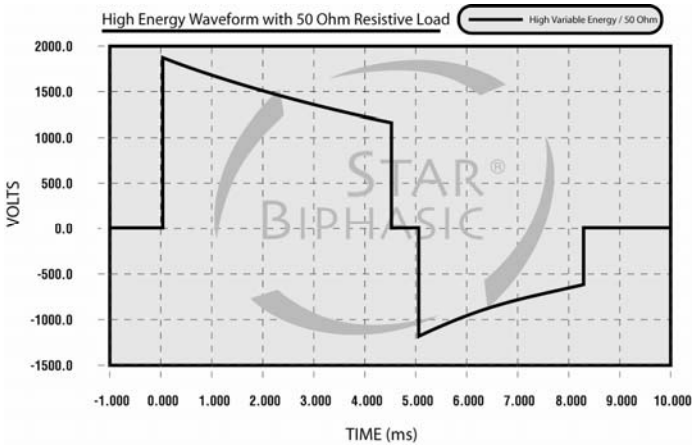
## STAR BIPHASIC WAVEFORM




The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. See table on next page for additional information.

## STAR BIPHASIC ENERGY PROTOCOLS FOR RESPONDER AED PRO

Cardiac Science's patented STAR® Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 25-180 Ohms. The AED Pro comes equipped with five different FDA cleared biphasic energy protocols.

The operator, with guidance, direction and implementation from its designated AED Pro program Medical Director, may select from one of these five protocols when placing the AED Pro into service. The AED Pro's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal). See next page.


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Figure A1. STAR BIPHASIC WAVEFORM

**Table A1 - Ultra-Low Current Responder AED Pro (all values are typical)**

| | Phase 1 | | Phase 2 | | |
|---|---|---|---|---|---|
| Patient's Impedance (Ohms) | Voltage (Volts) | Duration (ms) | Voltage (Volts) | Duration (ms) | Energy (Joules) |
| 25 | 1390 | 3.3 | 730 | 3.2 | 145-195 |
| 50 | 1420 | 4.5 | 915 | 3.2 | 130-175 |
| 75 | 1430 | 5.8 | 980 | 3.2 | 120-160 |
| 100 | 1435 | 7.0 | 1020 | 3.2 | 110-150 |
| 125 | 1440 | 8.3 | 1040 | 3.2 | 105-140 |

**Table A2 – Low Variable Energy Waveform Responder AED Pro (all values are typical**

| | Phase 1 | | Phase 2 | | |
|---|---|---|---|---|---|
| Patient's Impedance (Ohms) | Voltage (Volts) | Duration (ms) | Voltage (Volts) | Duration (ms) | Energy (Joules) |
| 25 | 1570 | 3.3 | 825 | 3.2 | 200-250 |
| 50 | 1600 | 4.5 | 1030 | 3.2 | 170-210 |
| 75 | 1610 | 5.8 | 1105 | 3.2 | 120-160 |
| 100 | 1615 | 7.0 | 1150 | 3.2 | 150-180 |
| 125 | 1620 | 8.3 | 1170 | 3.2 | 140-170 |

**Table A3 – High Variable Energy Waveform Responder AED Pro (all values are typical**

| | Phase 1 | | Phase 2 | | |
|---|---|---|---|---|---|
| Patient's Impedance (Ohms) | Voltage (Volts) | Duration (ms) | Voltage (Volts) | Duration (ms) | Energy (Joules) |
| 25 | 1885 | 3.3 | 990 | 3.2 | 265-360 |
| 50 | 1920 | 4.5 | 1240 | 3.2 | 235-320 |
| 75 | 1930 | 5.8 | 1325 | 3.2 | 215-295 |
| 100 | 1940 | 7.0 | 1380 | 3.2 | 200-270 |
| 125 | 1945 | 8.3 | 1405 | 3.2 | 190-260 |


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These Rescue Protocols are selected by using the ServiceLink software program. The five biphasic energy protocols available are as follows:

| Rescue Protocols | Shock Sequence[1] | Energy Level | Energy Range (J) |
|---|---|---|---|
| Factory Default | 1. | 200VE | 140J-250J |
| | 2. | 300VE | 190J-360J |
| | 3. | 300VE | 190J-360J |
| Protocol #2 | 1. | 200VE | 140J-250J |
| | 2. | 200VE | 140J-250J |
| | 3. | 300VE | 190J-360J |
| Protocol #3 | 1. | 150VE | 105J-195J |
| | 2. | 200VE | 140J-250J |
| | 3. | 200VE | 140J-250J |
| Protocol #4 | 1. | 150VE | 105J-195J |
| | 2. | 150VE | 105J-195J |
| | 3. | 200VE | 140J-250J |
| Protocol #5 | 1. | 200VE | 140J-250J |
| | 2. | 200VE | 140J-250J |
| | 3. | 200VE | 140J-250J |

## SAFETY STANDARDS

IEC 60601-1 (1998), Amendments 1 (1991) and 2 (1995); IEC 60601-2-4 (2002); IEC 60601-1-4 (2000)

## ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS

The Responder PRO meets the requirements of the following EMC standards, as required by IEC 60601-2-4.:

IEC 60601-1-2 (2001), Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: electromagnetic compatibility - Requirements and tests.

### EMISSIONS

Electromagnetic Fields: CISPR 11 (2003), Industrial, scientific and medical (ISM) radio-frequency equipment - radio disturbance characteristics - limits and methods of measurement; Group 1, Class B. IEC 60601-2-4 (2002), Section 36.201.1.

### IMMUNITY

Electromagnetic: IEC 61000-4-3 (2003), Electromagnetic compatibility (EMC) - part 4-3: Testing and measurement techniques - radiated, radio-frequency, electromagnetic field immunity test; Level 3 (10V/m) and X (20V/m). IEC 60601-2-4 (2002) Section 36.202.3.

Magnetic: IEC 61000-4-8 (1994), Electromagnetic compatibility (EMC) - part 4. Testing and measurement techniques - section 8. Power frequency magnetic field immunity test basic EMC publication; Level X (3 A/m). IEC 60601-2-4 (2002), Section 36.202.8.

ESD: IEC 61000-4-2 (2001), Electromagnetic compatibility (EMC) - part 4-2: testing and measurement techniques - electrostatic discharge immunity test; Level 3. IEC 60601-2-4 (2002), Section 36.202.2.

[1] The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.

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| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The AED PRO is intended for use in the electromagnetic environment specified below. The customer or the user of the AED PRO should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions<br><br>CISPR 11 | Group 1 | The AED PRO uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br><br>CISPR 11 | Class B | The AED PRO is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br><br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emissions<br><br>IEC 61000-3-3 | Not applicable | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | Not applicable | |
| Surge<br><br>IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | Not applicable | |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$) for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5% $U_T$<br>(>95% dip in $U_T$)<br>for 5 sec | Not applicable | |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 80 A/m | Power frequency magnetic fields should be at levels no higher than those characteristic of a typical location in typical heavy industrial and power plants and the control rooms of H.V. sub-stations. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |


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| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The AED PRO is intended for use in the electromagnetic environment specified below. The customer or the user of the AED PRO should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance** |
| Conducted RF<br><br>IEC 61000-4-6 | 3 Vrms<br><br>150 kHz to 80 MHz outside ISM bands[a]<br><br>10 Vrms<br><br>150 kHz to 80 MHz in ISM bands[a] | Not Applicable<br><br>Not Applicable | |
| Radiated RF<br><br>IEC 61000-4-3 | 10 V/m<br><br>80 MHz to 2.5 GHz | 10 V/m | d = 1.2 √P 80 MHz to 800 MHz<br><br>d = 2.3 √P 800 MHz to 2.5 GHz<br><br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b].<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |


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[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the AED PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED PRO.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the AED PRO**

The AED PRO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED PRO as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter**<br><br>**W** | **Separation distance according to frequency of transmitter**<br>m | | | |
|---|---|---|---|---|
| | **150 kHz to 80 MHz outside ISM bands**<br><br>$d = 1.2\sqrt{P}$ | **150 kHz to 80 MHz in ISM bands**<br><br>$d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz**<br><br>$d = 1.2\sqrt{P}$ | **800 MHz to 2.5 GHz**<br><br>$d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.


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# SECTION 7: ACCESSORIES

## OVERVIEW

This section contains a list of parts and software accessories for Responder AED Pro. To place an order, contact your representative or distributor.


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| AED PRO ACCESSORIES | 51 |


## RESPONDER AED Pro

Each Responder AED Pro package includes one automated external defibrillator, one pair of adult defibrillation pads, one disposable IntelliSense® battery, one Operator's Manual, one Service CD-ROM (with Service Manual, ServiceLink® customization software, and ServiceLink® Manual), and one RescueLink® event-review CD-ROM.

Responder AED Pro is available in more than twenty languages, with others being added on a regular basis. For a complete list of those available, contact your GE sales representative.

## AED PRO ACCESSORIES

| PART NUMBER | DESCRIPTION |
|---|---|
| 2019199-002 | Adult Defibrillation Pads with two-year shelf life |
| 2019199-003 | Pediatric Defibrillation Electrode with two-year shelf life |
| 2022102-201 | Service CD-ROM |
| 2022103-201 | RescueLink® CD-ROM |
| 2019204-011 | ECG Electrodes (3) |
| 2023678-001 | Responder AED Pro Infrared Adapter for PC |
| 2023681-001 | Responder AED Pro IntelliSense® Lithium battery |
| 2023488-001 | Responder AED Pro 3-lead ECG Cable Kit, AHA |
| 2024178-001 | Responder AED Pro 3-lead ECG Cable Kit, IEC |
| 2023489-001 | Responder AED Pro Rechargeable Battery |
| 2023490-001 | Responder AED Pro Battery Charger |


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# AED PRO ACCESSORIES (CONTINUED)

**AED DELIVERY SYSTEMS**

| | |
|---|---|
| 2019199-001 | Molded carrying case for Responder AED Pro |
| 2019615-001 | Ready Kit: includes nitrile gloves, razor, scissors, towel, 4” gauze, antiseptic wipes, one way filter mask |
| 2019199-005 | AED Wall mount storage case |
| 2019199-006 | AED Wall mount storage case with strobe light alarm |
| 2024178-001 | AED Pro 3-Lead ECG Cable Kit, IEC |
| 2024452-001 | Add-on Pouch for AED Carry Case |
| 2024454-001 | USB-to-Serial Adapter for Infrared Cable |
| 2024455-001 | Adapter for Zoll defibrillator electrodes |
| 2024456-001 | Adapter for Physio defibrillator electrodes |
| 2019199-004 | Wire Wall rack |

**EDUCATION ACCESSORIES**

| | |
|---|---|
| 2023682-001 | AED Pro Patient Simulator |


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# SECTION 8: CONTACT INFORMATION / CUSTOMER SERVICE

To order supplies or accessories, contact your representative or distributor. For technical support, contact your local GE customer service.
Please have the serial and model numbers available. The serial and model numbers are located on the back of the Responder PRO.

Responder PRO is manufactured for:

GE Medical Systems Information Technologies, Inc.
8200 West Tower Avenue, Milwaukee, WI 53223 USA
**Tel.: 800 558 7044 (USA only)**
Fax: 800 421 6841
**Canada Tel: 800 668 0732**

GE Medical Systems Information Technologies GmbH
Munzinger Str. 3, D-79111 Freiburg, Germany
**Tel.: +49 761 4543 0**
Fax: +49 761 4543 233

Responder PRO is manufactured by:

Cardiac Science Corporation
500 Burdick Parkway
Deerfield, WI 53531, USA

CE 0086

EC REP MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany
Tel: +49 511 62 62 86 30
Fax: +49 511 62 62 86 33

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# Responder AED Pro

automated external defibrillator